



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lior GEPSTEIN et al.

Serial No.: 10/759,734

Filed: 01/20/2004

For: METHODS OF GENERATING
HUMAN CARDIAC CELLS
AND TISSUES AND USES
THEREOF

Examiner: SINGH, ANOOP KUMAR

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Group Art Unit: 1632

§ Attorney Docket: 27395
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of
10/24/07

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10/29/07

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MICHAL AMIT
UNDER 37 CFR 1.132

I, Michal Amit, am a co-inventor of the above-identified application.

I have read the Office Action issued with respect to the above-identified application.

In the Office Action, the Examiner rejected claims 176-181, 186-189 and 194-195 under 35 U.S.C. 102 (a) over Kehat et al (*Circulation*, Supplement II, Vol. 102 NO. 18, October 31, 2000, abstract IDS, hereinafter "*Circulation*")

The Kehat publication is the work of Applicants which was published within one year of the filing date of the instant application and cannot be used against Applicants. *In re Katz*, 687 F.2d 450, 215 USPTO 14 (CCPA 1982).

Dorit Karsenti, Mirit Drukman, and Yair Feld, are identified as co-authors of the above *Circulation* article for their assistance in the development of the invention by carrying out assignments and work under the supervision and direction of myself and my co-inventors, and in their assistance in the preparation of the *Circulation* article, and were therefore not included as co-inventors.

As such, the *Circulation* reference cannot be used as prior art against the instant application since the publication described our own work and was published within one year of our filing date.



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DECLARATION OF MICHAL AMIT
UNDER 37 CFR 1.132

I am presently employed as a researcher at the Technion Institute of Technology, Haifa Israel, Faculty of Medicine and Rambam Medical Center, Stem Cell Center, where I am a Senior Scientist. I received my Ph.D. degree from the Technion Institute of Technology in Medical Sciences.

My research focuses on derivation and culturing of human embryonic stem cells. Since the beginning of my career, I have published 15 scientific articles in highly regarded journals and books and have presented my achievements at many international scientific conferences.

I am a member of the International Society for Stem Cell Research (ISSCR).

I am a co-inventor of the subject-matter claimed in the above-referenced U.S. patent application and a co-author of the Itskovitz-Eldor publication (Mol Med. 2000 Feb;6(2):88-95).

I have read the Official Action issued in the above-identified application.

In this Official Action, the Examiner has rejected claims 176-181, 186-189 and 194-195 under 35 U.S.C. 102(a) as being anticipated by Itskovitz-Eldor et al. supra. The Examiner states that Itskovitz-Eldor et al. teach an in vitro culture of human cells of cardio specific lineage obtained from human ES cells that shows the cardiac specific synchronous rhythmic activity.

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Alexandria, VA 22313-1450

DECLARATION OF JOSEPH ITSKOVICH-ELDOR
UNDER 37 CFR 1.131

I, Joseph Iiskovitz-Eldor, am a co-inventor of the above-identified application.

I have read the Office Action mailed on October 19, 2006 with respect to the above-identified application

In the Office Action, the Examiner rejected claims 176-177, 186-189 and 194-195 under 35 U.S.C. 102 (e) over Xu et al (US 2005/0164382A1)

As the Examiner noted in his action that the effective filing date of the Xu reference US 2005/0164382A1 is July 12, 2001, while the publication date of another reference cited by the Examiner, Kehat et al., (*Circulation*, Supplement II, Vol. 102 No. 18, October 31, 2000, abstract IDS, hereinafter "*Circulation*") is October 2000.

The aforementioned *Circulation* publication described the work of mine and my co-inventors, Izhak Kehat, Lior Gepstein, and Michal Amit, and discloses our invention. The *Circulation* article describes both the conception and reduction to practice, and thus the making, of the invention disclosed and claimed in the above-identified application, which application was filed on July 20, 2001, well within the one-year grace period permitted by U.S. Patent law.

The Xu et al patent application is therefore not prior art relative to our invention.

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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DECLARATION OF JOSEPH ITSKOVITZ-ELDOR
UNDER 37 CFR 1.132

I, Joseph Itskovitz-Eldor, am a co-inventor of the above-identified application.

I have read the Office Action issued with respect to the above-identified application.

In the Office Action, the Examiner rejected claims 176-181, 186-189 and 194-195 under 35 U.S.C. 102 (a) over Kehat et al (*Circulation*, Supplement II, Vol. 102 NO. 18, October 31, 2000; abstract IDS, hereinafter "*Circulation*")

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450DECLARATION OF LIOR GEPSTEIN
UNDER 37 CFR 1.131

I, Lior Gepstein, am a co-inventor of the above-identified application.

I have read the Office Action mailed on October 19, 2006 with respect to the above-identified application.

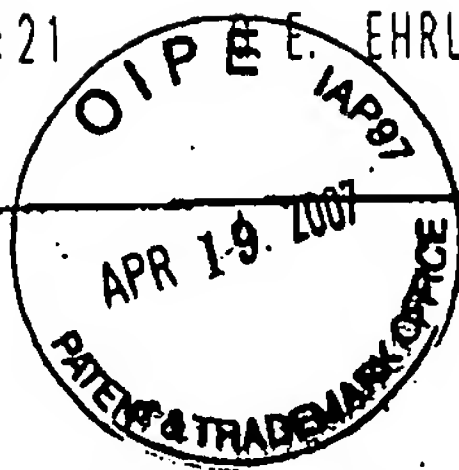
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As the Examiner noted in his action that the effective filing date of the Xu reference US 2005/0164382A1 is July 12, 2001, while the publication date of another reference cited by the Examiner, Kehat et al., (Circulation, Supplement 11, Vol. 102 No. 18, October 31, 2000, abstract IDS, hereinafter "Circulation") is October 2000.

The aforementioned Circulation publication described the work of mine and my co-inventors, Izhak Kehat, Michal Amit and Joseph Itskovich-Eldor, and discloses our invention. The Circulation article describes both the conception and reduction to practice, and thus the making, of the invention disclosed and claimed in the above-identified application, which application was filed on July 20, 2001, well within the one-year grace period permitted by U.S. Patent law.

The Xu et al patent application is therefore not prior art relative to our invention.

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**DECLARATION OF LIOR GEPSTEIN
UNDER 37 CFR 1.132**

I, Lior Gepstein, am a co-inventor of the above-identified application.

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF IZHAK KEHAT
UNDER 37 CFR 1.131

I, Izhak Kehat, am a co-inventor of the above-identified application.

I have read the Office Action mailed on October 19, 2006 with respect to the above-identified application

In the Office Action, the Examiner rejected claims 176-177, 186-189 and 194-195 under 35 U.S.C. 102 (e) over Xu et al (US 2005/0164382A1)

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THE UNIVERSITY OF CHICAGO

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Examiner: SINGH, ANOOP KUMAR

§ Attorney Docket: 27395

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF IZHAK KEHAT
UNDER 37 CFR 1.132

I, Kehat Izhak, am a co-inventor of the above-identified application.

I have read the Office Action issued with respect to the above-identified application

In the Office Action, the Examiner rejected claims 176-181, 186-189 and 194-195 under 35 U.S.C. 102 (a) over Kehat et al (*Circulation*, Supplement II, Vol. 102 NO. 18, October 31, 2000, abstract IDS, hereinafter "*Circulation*")

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